18th December 2023

Dear Healthcare Professional,

Shortage of GASTROGRAFIN amidotrizoate meglumine, sodium amidotrizoate oral liquid bottle (AUST R: 10684) and alternative supply arrangement under Section 19A of the Therapeutic Goods Act 1989.

Due to the shortages of the GASTROGRAFIN amidotrizoate meglumine, sodium amidotrizoate oral liquid bottle (AUST R: 10684) sponsored by Bayer Australia, Reach Pharmaceuticals has arranged the temporary supply of alternative products called **GASTROGRAFIN amidotrizoate meglumine, sodium amidotrizoate oral solution (Switzerland)** registered and marketed in the Switzerland.

GASTROGRAFIN amidotrizoate meglumine, sodium amidotrizoate oral solution (Switzerland) is not registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act,* 1989 until **30th April 2024** for the following indications:

> A contrast medium for examination of the gastrointestinal tract. It can be administered orally and as enema and is primarily indicated in cases in which the use barium sulfate is unsatisfactory, undesirable or contraindicated. Among these are: - suspected partial or complete stenosis - acute haemorrhage - threatening perforation (peptic ulcer, diverticulum) - other acute conditions which are likely to require surgery - after resection of the stomach or the intestine (danger of perforation or leak) - megacolon - visualisation of a foreign body or tumour before endoscopy - visualisation of gastrointestinal fistula. In addition to these conditions Gastrografin can generally be used for the same purposes as barium sulfate with the exception of the visualisation of mucosal diseases. Due to the insufficient coating properties of Gastrografin, barium sulfate should be used for single or double contrast techniques. In combination with barium sulfate, Gastrografin has considerably improved routine investigation of the gastrointestinal tract both from a diagnostic and from an organisational point of view - the latter by speeding up the examination. It is unsuitable only for the diagnosis of enteritis. Further indications: a) early diagnosis of a radiologically undetectable perforation or anastomotic defect in the oesophagus or gastrointestinal tract. b) Treatment of meconium ileus. c) Computerised tomography in the abdominal region. The danger of false diagnosis is significantly reduced if the intestine is opacified with Gastrografin, especially for differential diagnoses in the minor pelvis. Gastrografin facilitates delimitation of the intestine from neighbouring organs and permits an assessment of changes in the shape of the pancreas.

The labelling of the Swiss section 19A product is in German language. Both the ARTG product and the Swiss S19A products contain the same strength and active ingredients.
Please find below comparison between both the products.

	ARTG product GASTROGRAFIN amidotrizoate meglumine/sodium amidotrizoate oral liquid bottle (AUST R 10684)	**S19A product GASTROGRAFIN amidotrizoate meglumine, sodium amidotrizoate oral solution (Switzerland)**
Excipient Ingredients	- disodium edetate - saccharin sodium - polysorbate 80 - star anise oil - purified water	- disodium edetate - saccharin sodium - polysorbate 80 - star anise oil - purified water Total sodium content: 373.59 mg per 100 ml.
Storage	Store below 25 degrees Celsius.	Do not store above 25°C.

	Contrast medium solution not used within 72 hours after opening the bottle must be discarded. Protect from light and X-rays. **Instructions for Use/Handling** At temperatures below 7 °C Gastrografin tends to crystallise, but this can be reversed by gently warming and shaking the bottle. This phenomenon has no effect on the effectiveness or stability of the preparation.	Contrast solution that has not been used up 72 hours after opening the bottle must be discarded. Store away from light and x-rays. **Instructions for handling** At temperatures below +7 °C, Gastrografin tends to crystallize, but this can be reversible by gently warming and shaking. This does not affect the effectiveness and stability of the preparation. The preparation should be visually inspected for particles before administration. Only a clear, particle-free solution should be used.

Please refer to the Australian Product Information for **GASTROGRAFIN amidotrizoate meglumine, sodium amidotrizoate oral liquid bottle (AUST R: 10684)** (available at https://www.ebs.tga.gov.au) when prescribing and administering **GASTROGRAFIN amidotrizoate meglumine, sodium amidotrizoate oral solution (Switzerland)**.

Adverse Event Reporting
Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **GASTROGRAFIN amidotrizoate meglumine, sodium amidotrizoate oral solution (Switzerland)** should be reported by healthcare professionals and patients to our Medical Information. This information can also be reported to the TGA at https://www.tga.gov.au/reporting-problems.

Reach Pharmaceuticals Medical Information can be contacted by phone on **1800 255 306** or via email at medical@reach-pharma.com

For sales related enquiries, please contact us on sales@reach-pharma.com or call 0422 429 648.

We would appreciate if you could distribute this information to those in your organisation who prescribe the product.

Yours sincerely,
Reach Pharmaceuticals Pty Ltd